

Appl. No. 09/996,555  
Atty. Docket No. 8341  
Amdt. dated 5 November 2004  
Reply to Office Action of 25 August 2004  
Customer No. 27752

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

#### Listing of Claims:

1. (Currently Amended) A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal ~~comprising~~ consisting essentially of:

- a. a safe and effective amount of a therapeutically active agent;
- b. an inner coating layer selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:2, poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures thereof; and
- c. an outer coating layer, applied ~~directly~~ to the inner coating layer, said outer coating layer comprising an enteric polymer that begins to dissolve in an aqueous medium at a pH of less than about 7, said enteric polymer being selected from the group consisting of polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof;

wherein the inner coating layer is not the same as the outer coating layer;

wherein if the inner coating layer is poly(methacrylic acid, methyl methacrylate) 1:1 then the outer coating layer is not poly(methacrylic acid, methyl methacrylate) 1:2 or is not a mixture of poly(methacrylic acid, methyl methacrylate) 1:1 and poly(methacrylic acid, methyl methacrylate) 1:2; and

wherein the inner coating layer and the outer coating layer contain no therapeutically active agent.

2. (Original) The composition of claim 1 wherein the inner coating is poly(methacrylic acid, methyl methacrylate) 1:2.

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3. (Previously Presented) The composition of claim 1 wherein the outer coating layer is selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:1, and mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.
4. (Previously Presented) The composition of claim 3 wherein the outer coating layer is a mixture of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.
5. (Original) The composition of claim 1 wherein the total coating thickness of the inner and outer coating layers combined is from about 5 mg/cm<sup>2</sup> to about 40 mg/cm<sup>2</sup>.
6. (Original) The composition of claim 5 wherein the total coating thickness is from about 10 mg/cm<sup>2</sup> to about 15 mg/cm<sup>2</sup>.
7. (Original) The composition of claim 6 wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured.
8. (Previously Presented) The composition of claim 1 wherein the therapeutically active agent is selected from the group consisting of laxatives, anti-diarrheals, nonsteroidal anti-inflammatory agents, 5-amino salicylic acid, glucocorticoids, antimicrobials, immunosuppressants, chemotherapeutics or anti-cancer drugs, peptides, proteins, cardiovascular drugs, psychotropic drugs, H2-blockers, antiasthmatic agents, and antihistamines.
9. (Original) The composition of claim 8 wherein the therapeutically active agent is a nonsteroidal anti-inflammatory agent.
10. (Previously Presented) The composition of claim 9 wherein the therapeutically active agent is 5-amino salicylic acid.
11. (Currently Amended) A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal ~~comprising~~ consisting essentially of:

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- a. a safe and effective amount of a therapeutically active agent;
- b. an inner coating layer comprising poly(methacrylic acid, methyl methacrylate) 1:2;  
and
- c. an outer coating layer, applied ~~directly~~ to the inner coating, said outer coating layer comprising an enteric polymer that begins to dissolve in an aqueous medium at a pH of less than about 7, said enteric polymer being selected from the group consisting of polymethacrylates, anionic polymethacrylates, poly(methacrylic acid, methyl methacrylate) 1:1, mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1, polyvinyl acetate phthalate, poly(methacrylic acid, ethyl acrylate) 1:1, and compatible mixtures thereof;

wherein the inner coating layer is not the same as the outer layer coating.

12. (Cancelled)

13. (Cancelled)

14. (Previously Presented) The composition of claim 11 wherein the outer coating is selected from the group consisting of poly(methacrylic acid, methyl methacrylate) 1:1 and mixtures of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

15. (Original) The composition of claim 14 wherein the outer coating is a mixture of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

16. (Original) The composition of claim 11 wherein the total coating thickness of the inner and outer coating layers combined is from about 5 mg/cm<sup>2</sup> to about 40 mg/cm<sup>2</sup>.

17. (Original) The composition of claim 16 wherein the total coating thickness is from about 10 mg/cm<sup>2</sup> to about 15 mg/cm<sup>2</sup>.

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18. (Original) The composition of claim 17 wherein the solid dosage form is coated by continuous spray methods wherein the outer coating layer is applied after the inner coating layer but before the inner coating layer is dried or cured.
19. (Previously Presented) The composition of claim 11 wherein the therapeutically active agent is selected from the group consisting of laxatives, anti-diarrheals, nonsteroidal anti-inflammatory agents, 5-amino salicylic acid, glucocorticoids, antimicrobials, immunosuppressants, chemotherapeutics or anti-cancer drugs, peptides, proteins, cardiovascular drugs, psychotropic drugs, H2-blockers, antiasthmatic agents, and antihistamines.
20. (Original) The composition of claim 19 wherein the therapeutically active agent is a nonsteroidal anti-inflammatory agent.
21. (Previously Presented) The composition of claim 20 wherein the therapeutically active agent is 5-amino salicylic acid.
22. (Original) The composition of claim 11 wherein the solid dosage form is a compressed tablet.
23. (Previously Presented) A method of consistent and reliable delivery and release of a therapeutically active agent to the desired region of delivery by orally administering the composition of claim 1.
24. (Previously Presented) A method of consistent and reliable delivery and release of a therapeutically active agent to the desired region of delivery by orally administering the composition of claim 11.
25. (Previously Presented) The composition of claim 1 wherein the solid dosage form is a compressed tablet.
26. (Previously Presented) The composition of claim 1 wherein the solid unit dosage form has a total weight from about 600 mg to about 1200 mg.

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27. (Previously Presented) The composition of claim 10 wherein the 5-amino salicylic acid is present in an amount from about 700 mg to about 900 mg per solid unit dosage form.
28. (Previously Presented) The composition of claim 1 wherein the outer coating layer has a minimum thickness from about 10  $\mu\text{m}$  to about 200  $\mu\text{m}$ .
29. (Previously Presented) The composition of claim 4 wherein the outer coating layer has a minimum thickness from about 10  $\mu\text{m}$  to about 50  $\mu\text{m}$ .
30. (Previously Presented) The composition of claim 29 wherein the outer coating layer has a minimum thickness from about 20  $\mu\text{m}$  to about 40  $\mu\text{m}$ .
31. (Previously Presented) The composition of claim 11 wherein the solid unit dosage form has a total weight from about 600 mg to about 1200 mg.
32. (Previously Presented) The composition of claim 21 wherein the 5-amino salicylic acid is present in an amount from about 700 mg to about 900 mg per solid unit dosage form.
33. (Previously Presented) The composition of claim 11 wherein the outer coating layer has a minimum thickness from about 10  $\mu\text{m}$  to about 200  $\mu\text{m}$ .
34. (Previously Presented) The composition of claim 15 wherein the outer coating layer has a minimum thickness from about 10  $\mu\text{m}$  to about 50  $\mu\text{m}$ .
35. (Previously Presented) The composition of claim 34 wherein the outer coating layer has a minimum thickness from about 20  $\mu\text{m}$  to about 40  $\mu\text{m}$ .
36. (New) A pharmaceutical composition in a solid unit dosage form for oral administration in a human or lower animal consisting essentially of:
- a safe and effective amount of 5-amino salicylic acid;
  - an inner coating layer comprising poly(methacrylic acid, methyl methacrylate) 1:2;  
and
  - an outer coating layer, applied to the inner coating layer, said outer coating layer comprising an enteric polymer that begins to dissolve in an aqueous medium at a pH

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of less than about 7, said enteric polymer being a mixture of poly(methacrylic acid, methyl methacrylate) 1:2 and poly(methacrylic acid, methyl methacrylate) 1:1.

37. (New) A method of consistent and reliable delivery and release of 5-amino salicylic acid to the desired region of delivery by orally administering the composition of claim 36.